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10/584,510	05/14/2007	Robert Johan Joseph Hageman	0470-061930	4164

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EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
03/24/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@webblaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,510	HAGEMAN, ROBERT JOHAN JOSEPH	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-20 and 22-41* is/are pending in the application.

4a) Of the above claim(s) *34-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19 and 22-31* is/are rejected.

7)☒ Claim(s) *20,32,33,40 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A (Translation of EP 0 611 568)*.

DETAILED ACTION

Applicants' response of 12/21/2010 has been received and entered into the application file. Claims 18-20 and 22-32 have been amended; new claims 40 and 41 are entered; claim 21 has been cancelled. Claims 18-20 and 22-41 are pending in the instant application, of which claims 34-39 remain withdrawn from consideration, pursuant to 37 CFR 1.142(b) as being directed to non-elected subject matter, the election being made **without** traverse in the reply filed 3/17/2010.

Claims 18-20, 22-33 and 40-41 have been considered on the merits.

Applicants' remarks have been fully considered, each response will be addressed below, as appropriate. Rejections/objections not repeated herein are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The amendment to claims 18 and 23 have obviated the rejections previously of record under 35 USC 112, first paragraph, as lacking written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The amendments to the claims have obviated the rejections previously of record under 35 USC 112, second paragraph, as being indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Initially it is noted that an error was made in the calculations presented by the Examiner for the total tryptophan provided within 1 L of the composition of Larson, Applicants kindly provided the correct calculation, and it is noted that the amount of tryptophan present in 1 L of the composition of Larson is not within the range required by previous claim 21. However, noting that previous claim 21 only required at least one amino acid selected from the group recited (in the amount recited) to be present, and at least methionine was present in the amount specified by the claims, the rejection over claim 21 was still proper.

Regardless, the amendments to the instant claims, specifically the amendment to claim 18 to require the presence of each of methionine, lysine, tryptophan, and leucine (in the specified amounts), does serve to differentiate the currently claimed composition from each of the compositions disclosed by Larson and Verheul-Koot. Neither of the compositions of Larson nor Veheul-Koot include each of the amino acids in the specified amounts as currently required by claim 18; therefore all rejections previously of record under 35 USC 102(b)/(e) are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The claims are interpreted as being directed to a composition comprising:

a) 14-1000 mg pantothenic acid or a specific chemical equivalent thereof; and

b) a protein component, wherein the protein source provides at least 15% of the total caloric value of the composition, and wherein the protein component contains (per 100 g of total protein)

1.8-6 g methionine,

5.8-12.0 g lysine,

1.5-4.0 g tryptophan, and

at least 8 g leucine; and

c) optionally carbohydrates in an amount such that the carbohydrates provide 32-40% of the total caloric value of the composition; and

d) optionally lipids in an amount such that the lipids provide 18-25% of the total caloric value of the composition;

wherein the composition has a total caloric value of at least 100 kcal.

Please note that "En%" is being interpreted as the percentage of energy, in the form of calories, provided by each of the recited components; this is the best interpretation that can be determined given the information in the specification.

Furthermore, please note that the intended use of the composition "stimulation of appetite in humans" recited in the preamble is only considered in so far as the composition must be administrable to humans. See MPEP 2111.02.

Finally, though the claim states the composition is provided in a 'daily dosage form' because the claim fails to define the daily dosage form by any size, volume, formulation, etc, the term 'daily dosage

form' is not given patentable weight. Thus, the composition may have any size or form, so long as the composition contains at least 100 kcal.

Claims 18, 19 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al (EP 0611568; English language translation provided), in light of Priya Chemicals "Amino Acid Compositions" and Sindayikengera et al (J Zhejiang Univ Science B, 1996).

Schultz et al disclose an enteral feed composition for providing nutrition to oncological patients. The composition disclosed at Example 2 is relied upon for purposes of this rejection. The composition disclosed in Example 2 is 1000 mL in volume, and contains:

- 72.2 g of fat (of which 34.7% (48.06g) is saturated fat in the form of palmitic acid, stearic acid, caprylic acid and capric acid)
- 58.5 g of protein (of which 69.2% (40.5 g) is provided from sodium caseinate; 13.7% (8.0 g) is provided from yeast RNA; and 17.1% (10.0 g) is provided from whey protein hydrolysate)
- 104.0 g of carbohydrate
- 13.2 mg of calcium pantothenate

The composition has a caloric value of 1.3 kcal/mL; thus in 1000 mL the composition contains 1300 calories. The fat component provides 50% of the caloric energy (50 En%), the protein component provides 18% of the caloric energy (18 En%), and the carbohydrate component provides 32% of the caloric energy (32 En%). (See paragraph 0054). 1000 mL of the composition has a total weight of 1066.1 g (266.1 g of fat + protein + lipids + vitamins; 800 g water (800 mL, with 1 mL H20= 1 g).

Noting that the instant claims are not limited in volume or form, a double batch of the above disclosed formulation is being relied upon to read on "a daily dosage form." A double batch (i.e. 2000 mL) of the composition disclosed in Example 2 comprises:

- 144.4 g of fat (of which 34.7% (96.12g) is saturated fat in the form of palmitic acid, stearic acid, caprylic acid and capric acid)
- 107.0 g of protein (of which 69.2% (81.0 g) is provided from sodium caseinate; 13.7% (16.0 g) is provided from yeast RNA; and 17.1% (20.0 g) is provided from whey protein hydrolysate)
- 208.0 g of carbohydrate
- 26.4 mg of calcium pantothenate

2000 mL of the composition has a caloric value of 2600 calories. The fat component still provides 50% of the caloric energy (50 En%), the protein component still provides 18% of the caloric energy (18 En%), and the carbohydrate component still provides 32% of the caloric energy (32 En%). 2000 mL of the composition has a total weight of 2132.2 g.

The double batch of the formulation of Schultz et al satisfies the limitations of instant claim 18 with regards to the amount of calcium pantothenate (26.4 mg) (as one of the accepted equivalents of pantothenic acid); the En% provided by each of protein (18%), carbs (32%) and fat (lipids)(50%); and the total caloric value of the composition (2600 calories). The double batch formulation further satisfies the limitations of instant claim 19, noting the presence of whey proteins. The double batch formulation further satisfies the limitation of instant claims 24-26 with regards to the total caloric value (2600 calories). The double batch formulation satisfies the limitations of instant claims 27-29, in that it contains 144.4 g of fat (lipids), which constitute 6.77 wt% of the composition. The double batch formulation satisfies the limitation of instant claims 30 and 31 in that 34.7 wt% of the lipids are saturated fatty acids.

The formulation of Schultz et al differs from the composition of the instant claims with regards to the amino acid content of the protein component. The composition of Example 2 of Schultz et al is reported to contain sodium caseinate, yeast RNA and whey protein hydrolysate as the protein sources; however Schultz et al do not provide the specific source for each of these components, nor do they provide specific amino acid profiles for each of the protein components. The specific amino acid content of sodium caseinate and whey protein hydrolysate can vary based on the source (i.e. commercial source) and manufacturing procedure (See the amino acid composition for casein based protein reported by Priya Chemicals compared to the amino acid composition for sodium caseinate reported by Sindayikengera et al (Table 4)). Thus without specific disclosure of the particular amino acid content of the protein sources used by Schultz et al, such cannot be inferred. Thus the reference is not applied as anticipatory.

However, it is submitted that Schultz et al teach a number of protein sources which can be employed in their composition, including native or hydrolyzed forms of milk, pea, soy, whey, and salts of caseinates (See Schultz et al, paragraph 0025). It is therefore submitted that selection of any of the disclosed protein sources would have been appropriate for use in the composition of Schultz et al, so long as the total protein En% of 18% was achieved, as described by Schultz et al. The selection of different protein sources would provide various amino acid profiles (i.e. % of each amino acid based on total weight of the protein), and thus absent evidence of criticality of the instantly claimed ratios of amino acids, the claimed amounts are considered to be obvious over various protein sources which were contemplated by Schultz et al. Therefore the limitations of claim 18, 22 and 23, with regards to the amino acid compositions, are held to be prima facie obvious over the composition of Schultz et al, especially in the absence of evidence to the contrary.

Claim Objections

The amendments to claims 19 and 20 obviate the objections previously made thereagainst; however the amendment to claim 23 has necessitated the following new objection:

Claim 23 is objected to for a minor informality: In the 4th line of the claim "dimer" is misspelled "dimmer." Correction is required.

Claims 20, 32, 33, 40 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651